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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

<b>In Re Application of:</b>	G. David Jang
<b>Application No.:</b>	09/934,310
<b>Filed:</b>	August 9, 2001
<b>For:</b>	INTRAVASCULAR STENT
<b>Examiner:</b>	Paul B. Prebilic
<b>Group Art Unit:</b>	3738

**Docket No.:** S63.2-8429-US04

**BRIEF ON APPEAL**

This is a Brief on Appeal for the above-identified application in which all pending claims were rejected in an Office Action mailed May 20, 2004. Claims 34, 35, 37, 42-45 and 47 are pending in the application. An Amendment under 37 CFR §1.116 & 41.33 is included herewith canceling claims 39 and 40 without prejudice or disclaimer.

A Notice of Appeal was filed in this case on August 19, 2004. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

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**(i) Real Party in Interest**

The application is assigned to SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

**(ii) Related Appeals and Interferences**

At present there are no related appeals or interferences.

**(iii) Status of Claims**

Claims 1-33, 36, 38-41 and 46 have been canceled. Claims 34, 35, 37, 42-45 and 47 are pending, have been rejected and are the subject of this appeal. No claims have been allowed.

Claims 34, 35, 37, and 42-45 have been objected to.

Claims 39 and 40 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. An Amendment under 37 CFR §§1.116 & 41.33 is filed concurrently herewith wherein claims 39 and 40 are cancelled without prejudice or disclaimer.

Claims 34, 35, 37, 42-44 and 47 have been rejected under 35 U.S.C. §103(a) as being obvious over U.S. 6,348,065 to Brown et al in view of U.S. 5,575,818 to Pinchuk.

Claims 34, 35, 37, 39, 40, 42-45 and 47 have been rejected under 35 U.S.C. §103(a) as being obvious over U.S. 5,716,393 to Lindenberg et al in view of U.S. 5,575,818 to Pinchuk.

**(iv) Status of Amendments**

An Amendment under 37 CFR §1.116 & 41.33 is included herewith. In the Amendment claims 39 and 40 are cancelled without prejudice or disclaimer. In the Amendment After Final dated January 20, 2004, the cancellation of claims 39 and 40 was unintentionally overlooked as the claims should have been cancelled given that they would have been identical to claims 34 and 35 subsequent to the deletion of the word “continuously”. As indicated in the Amendment After Final Applicant intended to cancel the “continuously” tapered language from the claims in accordance with the discussion between Jonathan Grad and Supervisory Examiner McDermott. As such Applicants respectfully request that the Amendment included herewith be entered and claims 39 and 40 be cancelled prior to consideration of the arguments presented below. No other Amendments have been filed subsequent to the latest Office Action of May 20, 2004.

**(v) Summary of Claimed Subject Matter**

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

The invention of **claim 34** is directed to a stent having a first end [12; page 8, line 32 and Fig. 1A], an opposing second end [14; page 8, line 32 and Fig. 1A], and a longitudinal

length [16; page 8, line 32 and Fig. 1A], the stent comprising a plurality of annular elements [24; page 9, line 5 and Fig 1A], each annular element having a compressed state and an expanded state [page 9, lines 15-17]; and at least a portion of the stent having a tapered configuration in the expanded state [page 15, lines 4-5 and Fig. 5]; wherein the first and second ends have different degrees of flexibility [page 15, lines 27-32]; and wherein the stent is cut from a tube [page 25, lines 17-18].

The invention of **claim 35** is directed to the stent of claim 34 wherein each annular element [24; page 9, line 5 and Fig 1A] comprises a plurality of alternating struts [28; page 9, line 9 and Fig. 1A] and apices [30; page 9, lines 9-10 and Fig. 1A] connected to each other to form a substantially annular configuration, and wherein the stent further includes connecting members [38; page 9, line 28 and Fig. 1A] that are connected to the apices of the adjacent annular members.

The invention of **claim 37** is directed to the stent of claim 34 wherein the diameter of the stent increases from a first diameter at the first end to a second greater diameter at the second end [page 15, lines 7-9].

The invention of **claim 42** is directed to a stent having a first end [12; page 8, line 32 and Fig. 1A], an opposing second end [14; page 8, line 32 and Fig. 1A], and a longitudinal length [16; page 8, line 32 and Fig. 1A], the stent comprising a plurality of interconnected annular elements [24; page 9, line 5 and Fig 1A], each annular element having a compressed state [page 8, line 31] and an expanded state [page 9, lines 15-16]; wherein at least a portion of the stent has a tapered configuration in the expanded state [page 15, lines 4-5 and Fig. 5]; and

wherein the first and second ends have different degrees of flexibility [page 15, lines 27-32]; and wherein the stent is formed from a single piece of material [page 9, line 3].

The invention of **claim 43** is directed to the stent of claim 42 wherein each annular element [24; page 9, line 5 and Fig 1A] comprises a plurality of alternating struts [28; page 9, line 9 and Fig. 1A] and apices [30; page 9, lines 9-10 and Fig. 1A] connected to each other to form a substantially annular configuration.

The invention of **claim 44** is directed to the stent of claim 43 wherein the stent further includes connecting members [38; page 9, line 28 and Fig. 1A] that are connected to the apices [30; page 9, lines 9-10 and Fig. 1A] of the adjacent annular members [24; page 9, line 5 and Fig 1A].

The invention of **claim 45** is directed to the stent of claim 44 wherein the diameter of the stent increases from a first diameter at the first end to a second greater diameter at the second end [page 15, lines 7-9].

The invention of **claim 47** is directed to a stent having a first end [12; page 8, line 32 and Fig. 1A], an opposing second end [14; page 8, line 32 and Fig. 1A], and a longitudinal length [16; page 8, line 32 and Fig. 1A], the stent comprising a plurality of annular elements [24; page 9, line 5 and Fig 1A] including an end-most annular element at the first end and an end-most annular element at the second end [see Fig. 1A], each annular element having a compressed state [page 8, line 31] and an expanded state [page 9, lines 15-16]; and at least a portion of the stent having a tapered configuration in the expanded state [page 15, lines 4-5 and Fig. 5]; wherein the end-most annular element at the first end has a different degree of flexibility than the

end-most annular element at the second end [page 15, lines 27-32; different degrees of flexibility may also be provided by relief notches 98 as disclosed at page 17, lines 8-13 and Fig. 7B]; and wherein the stent is formed from a tube [page 25, lines 17-18].

**(vi) Grounds of Rejection to be Reviewed on Appeal**

I. Whether the Examiner erred in rejecting claims 34, 35, 37, 42-44 and 47 under 35 U.S.C. §103(a) as being obvious over U.S. 6,348,065 to Brown et al in view of U.S. 5,575,818 to Pinchuk.

II. Whether the Examiner erred in rejecting claims 34, 35, 37, 39, 40, 42-45 and 47 under 35 U.S.C. §103(a) as being obvious over U.S. 5,716,393 to Lindenberg et al in view of U.S. 5,575,818 to Pinchuk.

**(vii) Argument**

As indicated above claims 39 and 40 have been cancelled without prejudice or disclaimer in a co-filed Amendment under 37 CFR §§1.116 & 41.33, a copy of which is included herewith. Applicant respectfully requests that the Amendment canceling claims 39 and 40 be entered. In light of the Amendment filed herewith Applicant has directed the following comments to the rejections to the remaining pending claims: 34, 35, 37, 38, 42-45 and 47.

In addition to rejections to the instant claims, it is initially noted that in the Office Action claims 34, 35, 37 and 42-45 were *objected* to because the claims state that the stent has a tapered configuration in the expanded state, but in the Examiner's view only "each annular element" can have an expanded state and thus the expanded state of the stent lack antecedent

basis. Applicant notes that the Examiner also made this objection in the Final Office Action of October 31, 2003.

In responding to the Final Office Action of October 31, 2003, Applicant's representative Jonathan Grad interviewed both the Examiner and the Examiner's Supervisor, Corrine McDermott, on December 18, 200. In the interview with Supervisory Examiner McDermott, she indicated that the present antecedent basis objection was not necessary as the claim is understandable. A copy of Supervisory Examiner McDermott interview summary is included herewith. As a result of this interview, Applicant responded to the Final Office Action in an Amendment After Final mailed January 20, 2004, wherein the Applicant traversed the rejection based on Supervisory Examiner McDermott's comments.

Despite Applicant's response to the objection, the Examiner continues to object to the claims for the same reasons as were expressed in the Final Office Action of October 31, 2003. In light of the above however, Applicant respectfully asserts that the objection has been fully responded to, and as such respectfully requests that the objection be withdrawn.

Turning now to the remaining rejections, in the most recent Office Action of May 20, 2004 the Examiner rejected claims 34, 35, 37, 42-44 and 47 under 35 U.S.C. §103(a) as being obvious over U.S. 6,348,065 to Brown et al in view of U.S. 5,575,818 to Pinchuk. Though the actual rejection is stated as being based on the proposed combination of U.S. 6,348,065 to Brown et al in view of U.S. 5,575,818 to Pinchuk, the Examiner also alternatively asserts that the instant claims are rejected as being obvious over U.S. 6,348,065 to Brown et al alone. Both the stated rejection as well as the alternative rejection based on U.S. 6,348,065 to Brown et al by itself are both addressed below.

In the Office Action claims 34, 35, 37, 39, 40, 42-45 and 47 were rejected under 35 U.S.C. §103(a) as being obvious over U.S. 5,716,393 to Lindenberg et al in view of U.S. 5,575,818 to Pinchuk. As with the above rejection, in addition to the stated rejection the Examiner alternatively rejects the claims based on U.S. 5,716,393 to Lindenberg et al alone. Both the stated rejection and the alternative rejection are addressed below.

**I. The Examiner erred in rejecting claims 34, 35, 37, 42-44 and 47 under 35 U.S.C. §103(a) as being obvious over U.S. 6,348,065 to Brown et al in view of U.S. 5,575,818 to Pinchuk.**

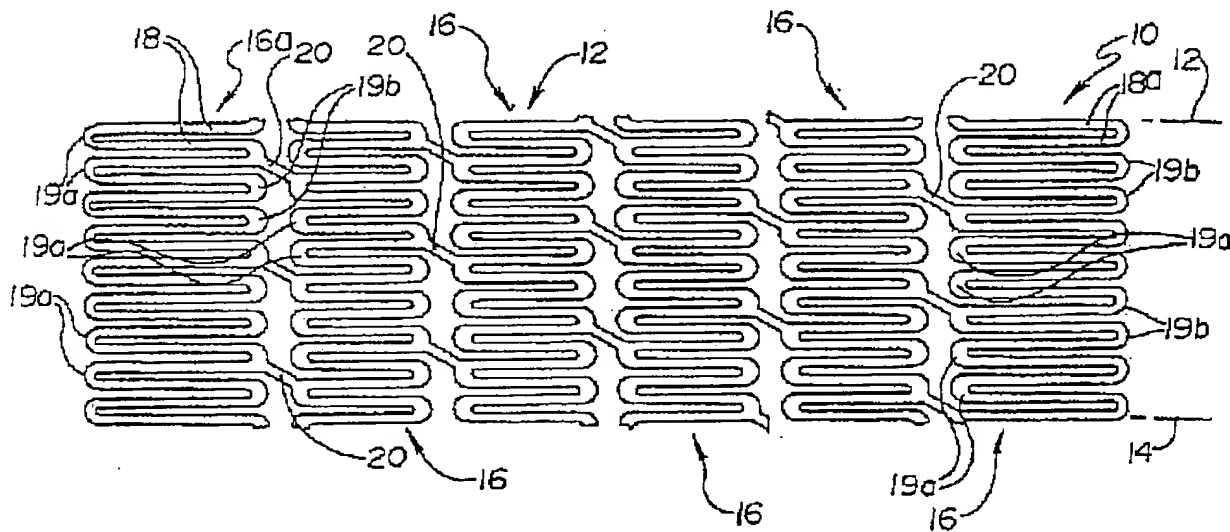
In rejecting the instant claims using the proposed combination of U.S. 6,348,065 to Brown et al (hereinafter: Brown or the Brown reference) in view of U.S. 5,575,818 to Pinchuk (hereinafter Pinchuk or the Pinchuk reference) the Examiner first states that "Brown discloses a stent made from a single piece of material...having ends with different flexibilities than the middle portions...but Brown fails to disclose first and second ends with different flexibilities." The Examiner goes on to explain that the "tapered configuration as claimed is between portions (19a) and struts (18) which are thinner as compared thereto." Next, regarding the formation of the stent, the Examiner notes that "the resulting structure of Brown would be substantially identical to that claimed such that it would be clearly obvious in view thereof."

Applicants respectfully assert that the Examiner's characterization of Brown is in error.



In regard to the Examiner's assertion that Brown discloses "[T]he tapered configuration claimed", Applicants have reprinted figure 4 of Brown below to show the portions (19a) and struts (18) where the Examiner asserts that Brown discloses the tapered configuration claimed.

**Fig. 4**



The Examiner is asserting that the illustration of one or more of the bends (19a) of a strut (18) is the stated disclosure of the "the tapered configuration as claimed."

Applicants assert, that the so-called tapered configuration of Brown is nothing more than an artifact of the drawing and that such an artifact is not indicative of any teaching or suggestion of a stent having tapered configuration on the part of Brown. No one of ordinary skill would interpret Brown as disclosing a stent having "a tapered configuration" as is presently claimed. Such an assertion is supported by the fact that nowhere in the Brown Application is there any discussion, description or even mention of a stent having a tapered configuration.

Brown does not describe such a configuration because such a configuration is simply not shown. This is in contrast to the present Application wherein in figure 5 and on page 5, line 4 to page 6, line 11 a stent having a tapered configuration is shown and described. It is made clear in the specification that a taper or tapering portion of the stent refers to the diameter of the stent or a portion thereof in the expanded state. Nowhere is there any indication or suggestion that a tapered configuration refers to a bend of a strut such as in the Examiner's interpretation of Brown. Thus, even if one were to interpret one or more of the bends (19a) of Brown as having a tapered shaped (intended or unintended as the case may be), such a tapered shape is not the tapered configuration shown, described, and claimed in the present Application.

As an alternative to using Brown alone to reject the instant claims, the Examiner seeks to combine the teachings of Pinchuk with the stent of Brown to render the instant claims obvious. In the Office Action the Examiner states that "it would have been obvious to make the ends of the Brown stent with different flexibilities for the same reasons that Pinchuk does the same and in order to fit the stent to a long section of blood vessel that tapers to a smaller diameter there along."

Regardless of why, or what motivation one would have to attempt make the proposed combination of Brown and Pinchuk, such a combination would not result in a hybrid device having all of the features of the stent described in the instant claims.

As indicated above, Brown does not teach a stent having a tapered configuration as presently claimed. Like, Brown, nowhere in the Pinchuk reference is a stent having a tapered configuration shown or described. As such the combination proposed by the Examiner will fail to teach or suggest all of the elements of the instant claims.

Furthermore, it should also be noted that in proposing the combination of Brown and Pinchuk the Examiner stated that "Pinchuk teaches that it was known to make similar stents with ends having different degrees of flexibility; see Figures 4, 5, and 7 as well as column 4, lines 24-65." Applicants respectfully assert that the Examiner's characterization of Pinchuk is also in error.

Nowhere does Pinchuk teach or suggest that the stent described therein has ends of different degrees of flexibility. The drawings cited show a stent having an end (or ends) which have a different braid pattern than the remainder of the stent but there is nothing in the description (the cited portion or elsewhere) that indicates that such a difference in the braid pattern results in different degrees of flexibility asserted by the Examiner. In the text cited by the Examiner Pinchuk describes a stent having portions with different radial pressure characteristics (column 4, line 27-29), and a portion with a locking ring which is comprised of a relatively short braid segment with a very obtuse pitch angle and which supplies a greater radial force than the rest of the stent (column 4, lines 58-65). There is nothing in the reference which suggests that either of these features would necessarily provide the ends of the stent with different degrees of flexibility as asserted by the Examiner. Consequently once again, even if the references were combined in the manner proposed by the Examiner it is clear that the resulting hybrid will not include all of the elements of the instant claims.

Thus, for all of the reasons discussed above Applicants assert that instant claims 34, 35, 37, 42-44 and 47 are patentable over the cited references.

II. The Examiner erred in rejecting claims 34, 35, 37, 39, 40, 42-45 and 47 under 35 U.S.C. §103(a) as being obvious over U.S. 5,716,393 to Lindenberg et al in view of U.S. 5,575,818 to Pinchuk.

As indicated above claims 39 and 40 have been cancelled without prejudice or disclaimer in a co-filed Amendment under 37 CFR §§1.116 & 41.33, a copy of which is included herewith. In light of this Amendment Applicant direct their comments to the remaining pending claims of 34, 35, 37, 42-45 and 47.

In the Office Action the Examiner states that "Lindenberg discloses a stent made from a single piece of material...having ends with different flexibilities than the middle portions...but Lindenberg fails to disclose first and second ends with different flexibilities." In discussing the process of manufacturing the stent the Examiner goes on to assert that "the resulting structure of Lindenberg would be substantially identical to that claimed such that it would be clearly obvious in view thereof."

This cannot possibly be obvious as Lindenberg and its "structure" do not teach or suggest a stent having "first and second ends with different flexibilities" as the Examiner himself clearly recognizes. To overcome this failure, the Examiner turns again to the Pinchuk reference for the concept that "Pinchuk teaches that it was well known to make similar stents with ends having different degrees of flexibility."

As discussed above in regard to the previous rejection, the Examiner's characterization of Pinchuk is believed to be in error. Nowhere does Pinchuk discuss or even mention flexibility or a stent whose ends have different flexibility. As previously mentioned, Pinchuk does in fact describe different characteristics between portions of a stent, but flexibility

is not one of them. In light of Pinchuk's failure to describe a stent having ends which have different flexibilities, even if there were some motivation to combine the references in the manner proposed in the Office Action it is clear that the resulting hybrid will not render the instant claims obvious.

As a result Applicants assert that instant claims 34, 35, 37, 42-45 and 47 are patentable over the cited references.

### CONCLUSION

Instant claims 34, 35, 37, 42-45 and 47 are patentably distinct over the asserted combination of Brown and Pinchuk, as well as the asserted combination of Lindenberg and Pinchuk. Consequently, reversal of the rejections under 35 U.S.C. §103 is respectfully requested.

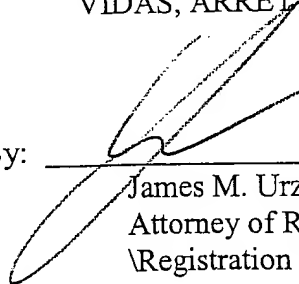
Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

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11/19/04

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**(viii) Claims Appendix**

Claim 34. A stent having a first end, an opposing second end, and a longitudinal length, the stent comprising:

a plurality of annular elements, each annular element having a compressed state

and an expanded state; and

at least a portion of the stent having a tapered configuration in the expanded state;

wherein the first and second ends have different degrees of flexibility; and

wherein the stent is cut from a tube.

Claim 35. The stent of claim 34, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the stent further includes connecting members that are connected to the apices of the adjacent annular members.

Claim 37. The stent of claim 34 wherein the diameter of the stent increases from a first diameter at the first end to a second greater diameter at the second end.

Claim 42. A stent having a first end, an opposing second end, and a longitudinal length, the stent comprising:

a plurality of interconnected annular elements, each annular element having a

compressed state and an expanded state; wherein at least a portion of the stent has

a tapered configuration in the expanded state; and wherein the first and second

ends have different degrees of flexibility; and wherein the stent is formed from a

single piece of material.

Claim 43. The stent of claim 42, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

Claim 44. The stent of claim 43, wherein the stent further includes connecting members that are connected to the apices of the adjacent annular members.

Claim 45. The stent of claim 44 wherein the diameter of the stent increases from a first diameter at the first end to a second greater diameter at the second end.

Claim 47. A stent having a first end, an opposing second end, and a longitudinal length, the stent comprising:

a plurality of annular elements including an end-most annular element at the first end and an end-most annular element at the second end, each annular element having a compressed state and an expanded state; and  
at least a portion of the stent having a tapered configuration in the expanded state;  
wherein the end-most annular element at the first end has a different degree of flexibility than the end-most annular element at the second end; and  
wherein the stent is formed from a tube.

**(ix) Evidence Appendix**

Not Applicable

**(x) Related Proceedings Appendix**

See the enclosed Amendment filed in accordance with 37 CFR §§1.116 & 41.33 wherein claims 39 and 40 have been cancelled without prejudice or disclaimer.